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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,134

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Thomas P. Jerussi

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EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,134	Applicant(s) JERUSSI ET AL.	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-78 is/are pending in the application.
- 4a) Of the above claim(s) 72-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 60-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/23/04, 11/25/03, 1/18/06</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 60-71, in the reply filed on 3 May 2007 is acknowledged. The traversal is on the ground(s) that a search of O-desmethylylvenlafaxine succinate will necessarily encompass the subject matter of both groups I and II. This is not found persuasive because Groups I and II comprise patentably distinct subject matter which each require search that is non-coextensive with that required for the other. The requirement is still deemed proper and is therefore made FINAL. Claims 72-78 are held withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 60-66 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husbands (US 4,535,186 08-1985 08-1985).

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Instantly claimed is O-desmethylvenlafaxine succinate and compositions thereof.

Husbands teaches (Column 19, lines 1-22) the synthesis of the compound O-desmethylvenlafaxine fumarate. Husbands teaches (Column 10, lines 31-61) pharmaceutical compositions, oral dosage forms such as tablets and aqueous solutions.

The difference between the instantly claims and Husbands is that Husbands does not specifically exemplify O-desmethylvenlafaxine succinate.

Husbands, however, further teaches (Column 2, lines 39-46) the equivalence of the fumaric acid and succinic acid salts. Husbands thereby suggests the substitution of the succinate counterion for the exemplified fumarate. The corresponding hydrates would inherently form upon exposure to ambient humidity or in aqueous solution.

One of ordinary skill in the art would have been motivated by the suggestion of Husbands to make the instantly claimed compound. Because of that suggestion there would have been a reasonable expectation for success. The instantly claimed O-desmethylvenlafaxine succinate is therefore *prima facie* obvious over the teachings of Husbands.

Thus the instantly claimed compound and compositions would have been obvious to one of ordinary skill in the art.

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3. Claims 67-59 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husbands (US 4,535,186 08-1985 08-1985) as applied to claims 60-66 and 70 above, and further in view of Sherman et al (US 6,274,171 08-2001).

Instantly claimed are sustained-release formulations of O-desmethylvenlafaxine succinate.

The difference between the teachings of Husbands and the instant claims is that Husbands does not contemplate the use of extended release formulations of O-desmethylvenlafaxine succinate while such are instantly claimed.

Sherman, however, teaches (Abstract) extended release formulations of venlafaxine hydrochloride. Sherman teaches (Column 3, lines 17-27) extended release formulations of venlafaxine and microcrystalline cellulose which the examiner considers a rate-determining polymer comprising monomeric glucose units. Sherman teaches (Column 12, lines 29-36, claim 17) coatings of hydroxypropylmethyl cellulose as well.

Thus one of ordinary skill in the art would have used the formulations of Sherman to produce more consistent blood concentrations of O-desmethylvenlafaxine succinate. Since such techniques are standard in the art there would have been a reasonable expectation for success.

Thus the instantly claimed compositions would have been obvious to one of ordinary skill in the art.

Claim Objections

4. Claim 69 is objected to because of the following informalities: The word "hydroxypropylmethylcellulose" is misspelled. Appropriate correction is required.

Conclusion


5. Claims 60-78 are pending. Claims 60- 71 are rejected. Claim 69 is objected to. Claims 72-78 are held withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Paul A. Zucker
Primary Examiner
Art Unit 1621